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10/748,448	12/30/2003	Jeff Ondria	1671-0285	2398
<div>28078      7590      09/18/2007</div> <div>MAGINOT, MOORE &amp; BECK, LLP</div> <div>CHASE TOWER</div> <div>111 MONUMENT CIRCLE</div> <div>SUITE 3250</div> <div>INDIANAPOLIS, IN 46204</div>				
			EXAMINER	
			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			09/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/748,448

Applicant(s)

ONDRLA ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

1. Applicants' amendment of claims 19, 27, 28, 32, and 33 in the reply filed on June 29, 2007 is acknowledged.

### *Claim Objections*

2. Claim 33 is objected to because of the following informality: please substitute "the internal bore" (see line 2) with --the internal bore of the mounting element-- (i.e., to avoid confusion with internal bore 16 of stem 12). Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Horber (WO 02/39932 A1; previously cited by the Examiner). For English translation see US 6,818,019 B2.

Referring to Figures 1, 3, and 9, Horber discloses a shoulder joint prosthesis comprising:

- (i) A stem (stem 15 of shaft piece 13) *configured to be implanted* within a bone, the stem including a first coupler bore (**first interpretation:** bore of disk 31; **second interpretation:** first half of joint cavity 19; **third interpretation:** bore of disk 31 + first half of joint cavity 19) therein with an interior wall portion which, when viewed in cross-section, extends in a line

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within a first bore portion (e.g., opening or entrance) from a proximal surface portion of the stem to a ledge (**first interpretation:** edge/ledge 37; **second interpretation:** edge/ledge 23) which defines a portion of the bore narrower than the first bore portion, wherein the ledge is located between the first bore portion and a second bore portion;

(ii) A joint component (head cap 29) having a bearing surface and defining a second coupler bore (see Figures 1 and 9);

(iii) A mounting element (collar piece 21) having (i) a proximal portion (e.g., collar extension 27) received within the second coupler bore of the joint component in a friction fit manner, and (ii) a spherical articulating portion (articulation spherical head 25, or spherical edge surface 97) located within the first bore portion; and

(iv) A fastener (**first interpretation:** disk 31; **second interpretation:** screw 105; **third interpretation:** clamping member 107; **fourth interpretation:** disk 31 + screw 105; **fifth interpretation:** disk 31 + screw 105 + clamping member 107) having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem.

The bearing surface of said joint component mates with a glenoid component (12). The “interior wall portion” could be: (i) a portion of the interior wall of the bore of disk 31; and (ii) a portion of the first half of joint cavity 19. Any of these “interior wall portions” extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line. Also, the articulating face of articulation head 25 touches the internal bore around substantially an entire perimeter of the internal bore defined by the intersection of a plane (note: the “plane” is not defined in the claim language) with the internal bore.

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**NOTE:** It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

**NOTE:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v.*

*Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

5. Claims 27-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS).

Referring to Figures 1-8 (particularly Figures 3-5), Glien et al. disclose a joint prosthesis comprising:

- a. A stem (stem 12) having a bone engagement portion and a surface facing the mating component of the joint, said surface defining a tapered bore (cavity 14 is tapered at 15, 16, 17, and its distal end);
- b. A head component (head 40) having a bearing surface (see Figures 3-5) and a tapered cavity (tapered cavity 41);
- c. A mounting element (character 20) having a proximal portion (tapered block 21, 28) *configured for engagement* (emphasis added to functional language) with said head component

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and an articulating portion (hemispherical ball joint 23) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said tapered bore and *to form* (emphasis added to functional language) a friction-fit engagement with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway (cavity 24) through said mounting element with an inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) at said articulating portion; and

d. A screw (screw 30) extending from said mounting element *for engagement* (emphasis added to functional language) to the stem when said articulating portion is disposed within said tapered bore. Said screw comprises a cylindrical rod 31 having threaded end 33 formed therein. Said screw further includes an underside *configured for articulating contact* (emphasis added to functional language) with said inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) of the mounting element. The spherical bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see Figures).

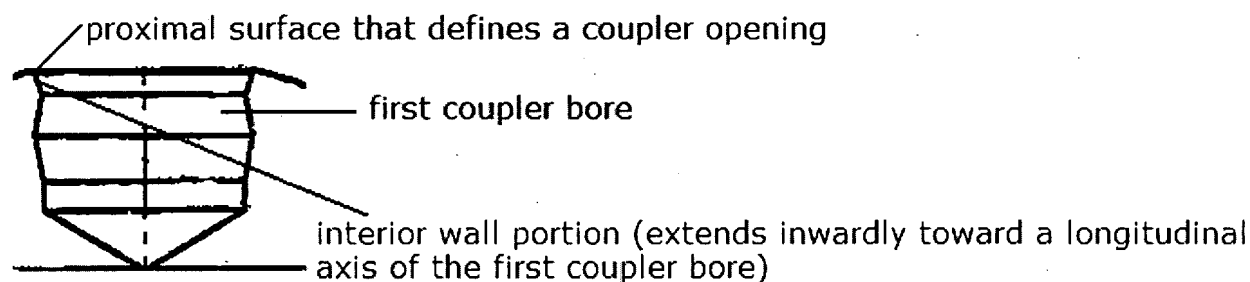
### ***Response to Arguments***

6. With regards to the 102(b) rejection based on Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS), Applicants' arguments filed June 29, 2007 have been fully considered but they are not persuasive.

a. With regards to claims 27 and 32, the Applicants argue that Glien et al. do not disclose or suggest: (i) the limitation "*includes an interior wall portion located within the first coupler bore*

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that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line” (see claim 27), and (ii) the limitation “a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem” (see claim 32). The Examiner respectfully disagrees. Below is a representation of Glien et al.’s Figure 3:



Based on this representation (and as seen in Figures 4 and 5), the “*spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line*”.

b. Regarding claim 32, the claim language does not define the “first portion” and the “second portion” of the fastener. A “portion” is a broad term. As an example, the “first portion” could be the first half of cylindrical rod 31, and the “second portion” could be the second half of cylindrical rod 31. As clearly shown in the Figures, the “second portion” interacts/couples with the stem.

7. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leonard et al. (US 6,228,120 B1; cited in Applicants’ IDS).

Referring to Figures 1-9 (particularly Figures 1-3), Leonard et al. disclose a joint prosthesis comprising:

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- a. A stem (stem 1) having a bone engagement portion (rod 2) and a surface (frontal face 4 of metaphysical section 3) facing the mating component of the joint, said surface defining a bore (cavity 7) and a threaded bore (threaded bore 8) aligned with said bore;
- b. A head component (head 20) having a bearing surface (see Figures 1-3) and a tapered cavity (tapered cavity 21);
- c. A mounting element (tapered swivel 12 + hemispherical ball joint 10) having a proximal portion (tapered swivel 12) *configured for engagement* (emphasis added to functional language) with said head component (see columns 6 and 7) and an articulating portion (hemispherical ball joint 10) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said bore (see columns 5 and 6) and *to form* (emphasis added to functional language) a friction-fit engagement (see column 6, lines 25-31) with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway (cavity 14) through said mounting element with an inner hemispherical bearing surface (hemispherical surface 10b) at said articulating portion; and
- d. A screw (locking unit 16) extending from said mounting element *for engagement* (emphasis added to functional language) to said threaded bore (see columns 6 and 7) when said articulating portion is disposed within said bore. Said screw comprises a cylindrical rod 17 having threaded end 17a formed therein. Said screw further includes hemispherical ball joint 18 (underside of head 19) *configured for articulating contact* (emphasis added to functional language) with internal/inner hemispherical surface 10b of hemispherical ball joint 10. The spherical bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see column 8, line 61 to column 9, line 24). The method



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for mounting said joint component to a bone is disclosed at column 8, line 48 to column 9, line 36. The method (particularly, position adjustment) could be performed with or without using a trial implant (see column 9, lines 37-48).

### ***Response to Arguments***

8. With regards to the 102(b) rejection based on Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS), Applicants' arguments filed June 29, 2007 have been fully considered but they are not persuasive.

a. With regards to claim 32, the Applicants argue that Leonard et al. do not disclose or suggest: the functional limitation "*the spherical articulating portion configured for press-fit engagement with the internal bore*" (see claim 32). The Examiner respectfully disagrees. Said limitation is not positively claiming a press-fit engagement. When screw 16 is completely inserted, it will press against the interior wall of the spherical articulating portion and is capable of expanding the spherical articulating portion outwardly against an interior wall portion of the internal bore or first coupler bore. The "tolerance" mentioned in column 6 at lines 60-64 will permit screw 16 to create a friction (press-fit) engagement between the spherical articulating portion and the internal bore.

**NOTE:** It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

**NOTE:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

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“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Bahler (WO 2001/22905; previously cited by the Examiner).

With regards to independent claim 19, Leonard et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing a ledge located between the first bore portion and the second bore portion. However, this is well known in the art. For example, both Horber (see US 6,818,019 for English translation) and Bahler disclose a stem having a coupling bore and a ledge (see Horber's Figures 1 and 10: character 23; see Bahler's Figure 1: character 29) located between a first bore portion and a second bore portion of said coupler bore in order to allow the articulating surface of a mounting element/ articulation body to rotate about an axis, while preventing a rolling movement of the articulation body in the articulation cavity.

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Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a stem having a coupling bore and a ledge located between a first bore portion and a second bore portion of said coupler bore, as taught by Horber and Bahler, with the stem of Leonard et al., in order to allow the articulating surface of a mounting element/ articulation body to rotate about an axis, while preventing a rolling movement of the articulation body in the articulation cavity.

### ***Response to Arguments***

11. With regards to the 103(a) rejection based on Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Bahler (WO 2001/22905; previously cited by the Examiner), Applicants' arguments filed June 29, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue that Leonard et al. do not disclose or suggest the functional limitation *"configured to force the spherical articulating portion outwardly from an axis of the first coupling bore and against the interior wall portion"* (see claim 19). The Examiner respectfully disagrees. Said limitation is not positively claiming the expansion of the spherical articulating portion. When screw 16 is completely inserted, it will press against the interior wall of the spherical articulating portion and is capable of expanding the spherical articulating portion outwardly against an interior wall portion of the internal bore or first coupler bore. The "tolerance" mentioned in column 6 at lines 60-64 will permit screw 16 to create a friction (press-fit) engagement between the spherical articulating portion and the internal bore.

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b. The Applicants argues: “*the proposed modification would eliminate the ability of the device of Leonard to provide all of the rotations. Therefore, the device would no longer provide continuous independent adjustments of the medial offset and the posterior offset*”. The Examiner respectfully disagrees. The proposed modification would not eliminate the ability of the device of Leonard to provide all of the rotations. The device will still be capable of moving (i.e., rotating) along different axes.

**NOTE:** It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

**NOTE:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

12. Claims 27-31 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS).

With regards to claims 27, Leonard et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing an interior wall portion located within the first

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coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line. However, this is well known in the art. For example, both Horber (see US 6,818,019 for English translation) and Glien et al. disclose a joint prosthesis comprising an interior wall portion (see Horber's Figures 1 and 10: character 25; see Glien et al.'s Figure 3: character 16) located within a first coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line in order to permit movement of the articulating surface of a mounting element/ articulation body in multiple degrees of freedom. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a joint prosthesis comprising an interior wall portion located within a first coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line, as taught by Horber and Glien et al., with the stem of Leonard et al., in order to permit movement of the articulating surface of a mounting element/ articulation body in multiple degrees of freedom.

### ***Response to Arguments***

13. With regards to the 103(a) rejection based on Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS), Applicants' arguments filed June 29, 2007 have been fully considered but they are not persuasive.

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a. With regards to claim 32, the Applicants argue that Leonard et al. do not disclose or suggest: the functional limitation “*the spherical articulating portion configured for press-fit engagement with the internal bore*” (see claim 32). The Examiner respectfully disagrees. Said limitation is not positively claiming a press-fit engagement. When screw 16 is completely inserted, it will press against the interior wall of the spherical articulating portion and is capable of expanding the spherical articulating portion outwardly against an interior wall portion of the internal bore or first coupler bore. The “tolerance” mentioned in column 6 at lines 60-64 will permit screw 16 to create a friction (press-fit) engagement between the spherical articulating portion and the internal bore.

b. As shown/disclosed above, Glien et al. (DE 101 23 517 C1; cited in Applicants’ IDS) does disclose an interior wall portion as recited in claim 27. It has not been mischaracterized.

c. The Examiner did provide motivation to combine the references. Further, the proposed modification would not eliminate the ability of the device of Leonard to provide all of the rotations. The device will still be capable of moving (i.e., rotating) along different axes.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Javier G. Blanco



September 9, 2007



David H. Willse  
Primary Examiner